

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NORTH CAROLINA
SOUTHERN DIVISION

No. 7:23-CV-897

IN RE:)
)
CAMP LEJEUNE WATER LITIGATION)
)
This Documents Relates to:)
ALL CASES)

O R D E R

This matter is before the court on Plaintiffs' motion to compel production of a draft Cancer Incidence Study ("CIS") by the Agency for Toxic Substances and Disease Registry ("ATSDR") and related material. [DE-64]. Defendant opposes the motion. [DE-74]. The motion is ripe and referred to the undersigned for disposition. For the reasons stated below, Plaintiffs' motion is denied.

I. Background

This litigation concerns the more than one thousand individual lawsuits filed under the Camp Lejeune Justice Act ("CLJA") in this district. *See* Pub. L. No. 117-168, § 804, 135 Stat. 1759, 1802-04. With the CLJA, Congress created a new federal cause of action permitting "appropriate relief for harm that was caused by exposure to the water at Camp Lejeune" for individuals who resided, worked, or were otherwise exposed for not less than 30 days during the period between August 1, 1953, and December 31, 1987. *See id.* § 804(b). To better manage this litigation, the court appointed a Plaintiffs' Leadership Group ("Plaintiffs"), *see* [DE-10], and entered case management orders streamlining pretrial procedures in all CLJA cases. *See e.g.*, [DE-23]. The court also established a discovery dispute protocol. [DE-55].

In the instant dispute, Plaintiffs assert that Defendant is improperly withholding “the current [CIS] draft [and related documents] . . . in response to Plaintiffs’ Request Number 1 to Plaintiffs’ Second Request for Production of Documents.” [DE-64] at 1. RFP 1 to Plaintiffs’ Second Request for Production of Documents reads in relevant part:

Please produce all Documents and ESI as defined above, including but not limited to all Communications, in Defendant’s possession, custody, or control, regarding any past, current, draft, planned or future study or report (including any supporting data), whether completed or uncompleted, published or unpublished, approved for dissemination or not, that examines, in whole or in part, the impact on human health of PCE, TCE, vinyl chloride, benzene, dichloroethylene, and/or any other volatile organic compounds present in the water at Camp Lejeune between August 1, 1953 and December 13, 1987, performed by [] a United States governmental entity including but not limited too [sic] ATSDR . . . It also intended to capture amongst other responsive information and documents, all documents and emails related to any unreleased ATSDR studies . . .

[DE-64-1] at 89.

There is no dispute that ATSDR is in possession of a draft CIS, undertaken “to determine whether residential workplace exposures to the drinking water contaminants at Camp Lejeune are associated with increased risks of specific cancers in Marines/Navy Personnel and civilian employees.” [DE-74-1] at ¶ 5. Defendants have submitted a declaration by Dr. Aaron Bernstein, Director of the National Center for Environmental Health for the Center for Disease Control and Prevention (“CDC”) and Director for ATSDR, who details the CIS within ATSDR’s process. [DE-74-1]. Dr. Bernstein states that the CIS is currently “undergoing peer review,” which ATSDR’s authorizing statute requires it to do. [DE-74-1] at ¶ 7 (citing 42 U.S.C. § 9604(i)(13)). After this “external peer review,” the CIS “will be submitted to the CDC scientific clearance system for ATSDR and CDC review and approval.” *Id.* at ¶ 8. Accordingly, Defendant asserts that the documents in question are protected by the deliberative process privilege.

II. Standard of Review

A. General Discovery Principles

The general rule regarding the scope of discovery is found in Fed. R. Civ. P. 26(b)(1):

Parties may obtain discovery regarding any nonprivileged matter that is relevant to any party's claim or defense and proportional to the needs of the case, considering the importance of the issues at stake in the action, the amount in controversy, the parties' relative access to relevant information, the parties' resources, the importance of the discovery in resolving the issues, and whether the burden or expense of the proposed discovery outweighs its likely benefit. Information within this scope of discovery need not be admissible in evidence to be discoverable.

"Relevancy under this rule has been broadly construed to encompass any possibility that the information sought may be relevant to the claim or defense of any party." *Prasad v. Nallapati*, 597 F. Supp. 3d 842, 846 (E.D.N.C. 2022) (first quoting *Equal Emp't Opportunity Comm'n v. Sheffield Fin. LLC*, No. 1:06-CV-889, 2007 WL 1726560, at *3 (M.D.N.C. June 13, 2007); then citing *Mainstreet Collection, Inc. v. Kirkland's, Inc.*, 270 F.R.D. 238, 240 (E.D.N.C. 2010) ("During discovery, relevance is broadly construed 'to encompass any matter that bears on, or that reasonably could lead to other matter that could bear on, any issue that is or may be in the case.'") (quoting *Oppenheimer Fund, Inc. v. Sanders*, 437 U.S. 340, 351 (1978))). Nevertheless, "[t]he parties and the court have a collective responsibility to consider the proportionality of all discovery and consider it in resolving discovery disputes." *Walls v. Ford Motor Co.*, No. 1:20CV98, 2021 WL 1723154, at *4 (M.D.N.C. Apr. 30, 2021) (citations omitted).

"Additionally, the court has 'substantial discretion' to grant or deny motions to compel discovery." *English v. Johns*, No. 5:11-CT-3206-D, 2014 WL 555661, at *4 (E.D.N.C. Feb. 11, 2014) (quoting *Lone Star Steakhouse & Saloon, Inc. v. Alpha of Va., Inc.*, 43 F.3d 922, 929 (4th Cir. 1995)). Simply because "requested information is discoverable under Rule 26 does not mean that discovery must be had." *Nicholas v. Wyndham Int'l Inc.*, 373 F.3d 537, 543 (4th Cir. 2004).

District courts must limit “‘the frequency or extent of discovery otherwise allowed’ if . . . ‘(i) the discovery sought is unreasonably cumulative or duplicative, or can be obtained from some other source that is more convenient, less burdensome, or less expensive; (ii) the party seeking discovery has had ample opportunity to obtain the information by discovery in the action; or (iii) the proposed discovery is outside the scope permitted by Rule 26(b)(1).’” *Page v. Bragg Communities, LLC*, No. 5:20-CV-336-D, 2023 WL 5418716, at *2 (E.D.N.C. Aug. 22, 2023) (quoting Fed. R. Civ. P. 26(b)(2)(C)).

B. Deliberative Process Privilege

The deliberative process privilege protects “documents reflecting advisory opinions, recommendations and deliberations comprising part of a process by which governmental decisions and policies are formulated.” *Heyer v. U.S. Bureau of Prisons*, No. 5:11-CT-03118-D, 2014 WL 4545946, at *2 (E.D.N.C. Sept. 12, 2014) (quoting *NLRB v. Sears, Roebuck & Co.*, 421 U.S. 132, 150 (1975)); see *United States v. Bertie Ambulance Serv., Inc.*, No. 2:14-CV-53-F, 2015 WL 3932167, at *3 (E.D.N.C. June 25, 2015).¹ The privilege “rests on the obvious realization that officials will not communicate candidly among themselves if each remark is a potential item of discovery and front page news, and its object is to enhance the quality of agency decisions by protecting open and frank discussion among those who make them within the Government.” *Dep’t of the Interior v. Klamath Water Users Protective Ass’n*, 532 U.S. 1, 8–9 (2001) (quotations omitted). It also “prevents public confusion that might result from the premature release of such nonbinding deliberations.” *City of Va. Beach v. U.S. Dept. of Com.*, 995 F.2d 1247, 1252–53 (4th

¹ The deliberative process privilege is often discussed within the context of document disclosure pursuant to the Freedom of Information Act (“FOIA”), as the fifth FOIA disclosure exemption “incorporates the privileges available to Government agencies in civil litigation . . . includ[ing] the deliberative process privilege.” *United States Fish & Wildlife Serv. v. Sierra Club, Inc.*, 592 U.S. 261, 267 (2021).

Cir. 1993). The privilege is about preserving the deliberative process itself: “each assertion of the privilege must be checked against the details of the deliberative process and the role of the documents to that process.” *Cipollone v. Liggett Grp. Inc.*, 812 F.2d 1400 (Table) (4th Cir. 1987) (citations omitted). Thus, “purely factual information” may still be privileged if it is “inextricably intertwined with deliberative material.” *Stone v. Trump*, 356 F. Supp. 3d 505, 514 (D. Md. 2018), *amended on reconsideration*, 402 F. Supp. 3d 153 (D. Md. 2019).

To qualify under the privilege, documents must be “deliberative,” meaning they are “prepared to help the agency formulate its position.” *United States Fish & Wildlife Serv.*, 592 U.S. 261 at 268 (citing *Sears*, 421 U.S. at 150–152). They must also be “predecisional,” or “prepared to assist in the arrival at a final decision.” *Heyer*, 2014 WL 4545946 at *3. However, “there is considerable overlap between these two prongs because a document cannot be deliberative unless it is predecisional.” *United States Fish & Wildlife Serv.*, 592 U.S. at 268.

The deliberative process privilege is qualified; plaintiffs may overcome it by “establish[ing] the existence of a sufficient need for the information that outweighs any harm from its production” *Id.* “In striking this balance, the common law of discovery developed a number of factors for the court to consider, including: (1) the relevance of the evidence to the lawsuit; (2) the availability of alternative evidence on the same matters; (3) the government’s role (if any) in the litigation, and (4) the extent to which disclosure would hinder frank and independent discussion regarding contemplated policies and decisions.” *Stone v. Trump*, 453 F. Supp. 3d 758, 766 (D. Md. 2020) (quoting *Cipollone*, 812 F.2d 1400 (Table)).

III. Discussion

A. The Draft CIS and Related Documents Fall Under the Deliberate Process Privilege.

Based on the excerpted privilege log, [DE-74-2], and Declaration by Dr. Bernstein, [DE-

74-1], the court finds that Defendant has met its burden showing that the draft CIS and related documents are privileged.

Defendant asserts that of the 30 documents withheld, 26 contain “revisions,” “comments,” or else are directly related to the peer review process. [DE-74-2]. For example, 11 out of the 30 documents contain “ATSDR’s internal revisions to the draft cohort study manuscript.” *Id.* The four remaining documents are “[d]ata files containing ATSDR’s analyses of the data underlying the [draft CIS].” *Id.* Defendant asserts that the data files “reveal the agency’s deliberations about what scientifically valid and reliable findings and conclusions may be drawn” *Id.*

First, the documents in question are deliberative. ATSDR is directed by statute to “establish and maintain inventory of literature, research, and studies on the health effects of toxic substances.” 42 U.S.C. § 9604(i)(1)(B). Those “studies and results of research . . . shall be reported or adopted only after appropriate peer review.” *Id.* § 9604(i)(13). After, “per [the] standard decision-making processes, the [CIS] will be submitted to the CDC scientific clearance system for ATSDR and CDC review and approval. ATSDR study authors will review and respond to comments on the report and make any necessary revisions based on the reviewer comments.” [DE-74-2] at ¶ 8. Only after clearing these multiple reviews—and receiving “approval” from ATSDR and CDC—may the CIS join the “inventory of literature, research, and studies” kept by the agency.² Whether the CIS in its current form does so is the statutory prerogative of ATSDR. All the documents identified by Defendant are deliberative; they are “prepared to help the agency formulate its position,” specifically, to publish a hypothetical final CIS. *United States Fish & Wildlife Serv.*, 592 U.S. at 268 (citation omitted); *see also Formaldehyde Inst. v. Dep’t of Health*

² An agency’s decision to publish has been upheld by numerous courts as an adequate basis for applying the privilege. *See Hooker v. U.S. Dep’t of Health & Hum. Servs.*, 887 F. Supp. 2d 40, 57 (D.D.C. 2012), *aff’d*, No. 13-5280, 2014 WL 3014213 (D.C. Cir. May 13, 2014) (collecting cases).

& Hum. Servs., 889 F.2d 1118, 1124 (D.C. Cir. 1989) (upholding privilege where “the deliberative decision [in question was] about whether and in what form to publish the Report in the name of [HHS].”).

The data files identified on Defendant’s privilege log are no exception. Regarding the data files, Dr. Bernstein states:

[T]he data and analytical files are part of the deliberative review and intertwined with the Cancer Incidence Study’s analysis. Release of the data would reveal much of the agency’s deliberation about the study findings. The collection and management of this data is also intertwined in the ATSDR study authors’ preliminary analysis and draft conclusions.

[DE-74-1] at ¶ 9. Defendant further asserts these are not simply data lists but contain “ATSDR’s analyses of the [underlying] data.” [DE-74-2] at 2. Though the privilege “does not protect purely factual information,” it applies where those facts are “inextricably intertwined with deliberative material.” *Stone*, 356 F. Supp. 3d at 514. Restated, where documents containing “[selective] facts . . . reveal the deliberative process,” they are protected. *Farmworkers Legal Servs. of N.C., Inc. v. U.S. Dep’t of Lab.*, 639 F. Supp. 1368, 1373 (E.D.N.C. 1986) (applying privilege to “fact summar[ies]” and “lists” “used to aid [agency] in . . . mak[ing] a decision . . . ”); *see also Blank Rome LLP v. Dep’t of the Air Force*, No. 15-CV-1200-RCL, 2016 WL 5108016, at *12 (D.D.C. Sept. 20, 2016) (finding “calculations and estimates . . . used in [agency’s] decision” regarding settlement proposal were privileged). Data files containing “analyses” which “reveal the agency’s deliberations” regarding the final scientific opinions and conclusions in the CIS are deliberative.

Second, the documents are all “predecisional”; there is no dispute that the CIS has not been added to ATSDR’s “inventory of [scientific] literature.” In *United States Fish & Wildlife Serv.*, the Supreme Court held that the deliberative process privilege applied to “draft biological opinions” and “draft documents” where the EPA’s “regulatory process . . . distinguished between

draft and final biological opinions by separating the steps at which each is produced.” 592 U.S. at 269-70. The court identified statutory provisions “specifically contemplat[ing] further review by the agency after receipt of the draft, and with it, the possibility of changes to the [] opinion . . . ,” which confirmed that the draft opinions were not the EPA’s final positions. *Id.* Likewise, ATSDR must undertake multiple layers of review before the agency can publish. 42 U.S.C. § 9604(i)(13); [DE-74-1] at ¶ 8. The CIS is undergoing this review currently. Its content may change substantially before the review is complete. It does not reflect a final agency decision so both it and the related materials are predecisional.

In sum, the court determines that Defendant has met its burden and the deliberative process privilege applies to all documents identified on Defendant’s privilege log relating to the CIS. *See* [DE-74-2].

B. The *Cipollone* Balancing Factors Weigh in Favor of Upholding the Privilege.

Plaintiffs’ contention that the *Cipollone* factors support abrogating the privilege in this instance is unavailing. When balancing the “public interest in nondisclosure with the need for the information as evidence,” the court considers “(1) the relevance of the evidence to the lawsuit; (2) the availability of alternative evidence on the same matters; (3) the government’s role (if any) in the litigation, and (4) the extent to which disclosure would hinder frank and independent discussion regarding contemplated policies and decisions.” *Stone*, 453 F. Supp. 3d at 766 (identifying *Cipollone* factors); *see also Heyer*, 2014 WL 4545946, at *5 (applying four-factor test). The court takes each of these in turn.

Factor one—relevance—weighs in Plaintiffs’ favor. However, Defendant is correct that the CIS is “just one of numerous studies regarding potential health effects from exposure to water at Camp Lejeune.” [DE-74] at 10. For example, ATSDR’s website identifies 22 different studies

that link exposure to the toxic chemicals found at Camp Lejeune with various “health effects,” including multiple cancers.³ Even so, Defendant admits that the CIS concerns “the evaluation of cancer incidence among Marines and Navy personnel exposed to contaminated drinking water at . . . Camp Lejeune . . .” [DE-74-2] at 2. Query what evidentiary weight the court would give a non-final CIS. Still, any scientific work conducted by a federal agency “evaluating cancer incidence” in individuals on base is plainly relevant for many active cases in this district.

Factor two goes to availability of the evidence and the existence of potential alternatives. Defendant contends that Plaintiffs may have access to “the data underpinning the draft CIS,” including “data collected from each state’s cancer registry.” [DE-74] at 11. And as previously discussed, Plaintiffs have access to multiple other studies linking exposure to the toxic chemicals found at Camp Lejeune with various diseases and health effects, including multiple cancers. *See e.g.*, ATSDR, *supra* n3. However, there is no dispute that the draft CIS and supporting documents identified on Defendant’s privilege log are in the exclusive possession of ATSDR and unavailable to Plaintiffs. On balance, factor two does not weigh in favor of either party.

Factor three weighs in Plaintiffs’ favor, as the government is the Defendant in this litigation and at all relevant times controlled day-to-day operations at Camp Lejeune.

The fourth factor, however—the chilling effect of disclosure—weighs heavily in favor of Defendant. Dr. Weinstein states in his declaration that releasing the non-final CIS would “suppress the routine scientific review process and have a chilling effect on deliberations.” [DE-74-1] at ¶ 10. That scientific review is mandated by statute and involves multiple independent experts “mak[ing] any necessary revisions based on reviewer comments, and, when recommended, []

³ ATSDR, *Health effects linked with trichloroethylene (TCE), tetrachloroethylene (PCE), benzene, and vinyl chloride exposure*, https://www.atsdr.cdc.gov/sites/lejeune/tce_pce.html (last visited Dec. 18, 2023).

undertak[ing] additional analyses.” *Id.* at ¶ 7 (citing 2 U.S.C. 9604(i)(13)). According to Dr. Weinstein, this is in part to “protect the scientific process and integrity of the study to be published.” *Id.*

Concern for the integrity of the scientific review process is not isolated to the present dispute. For example, the D.C. Circuit upheld the privilege for a three page “Review Letter . . . containing the comments of two referees” for a scientific journal which “reviewed a report that a [CDC] staff member had submitted for possible publication.” *Formaldehyde Inst.*, 889 F.2d at 1120. The court’s rationale was largely based on its concern for the integrity of the mandated review process:

[Agency] personnel acting in light of the agency’s Congressional mandate must regularly rely on the comments of expert scientists to help them evaluate the readiness of agency work for publication . . . There is [] unrefuted evidence in the record that release of reviewers’ editorial comments would very likely have a chilling effect on either the candor of potential reviewers of government-submitted articles or on the ability of the government to have its work considered for review at all. Furthermore, a government author is likely to be less willing to submit her work to a refereed journal at all if critical reviews could come to light somewhere down the line. This would result in the publication of inferior work . . .

Id. at 1125. This apprehension is warranted here, where tens of thousands of individuals may be implicated by ATSDR’s CIS, and likely many more by any future agency study of Camp Lejeune water exposure.

Moreover, the privilege is designed to “prevent[] public confusion that might result from the premature release of [] nonbinding deliberations,” such as the draft CIS. *City of Va. Beach*, 995 F.2d at 1252–53. Plaintiffs’ citation to a Reuters news article reporting on the existence of the draft CIS demonstrates this information has public and media interest. *See* [DE-65] at n4. Thus, there is risk that compelling production of an incomplete CIS subject to change would garner significant attention and result in “public confusion,” as well as “undermine the public’s trust in

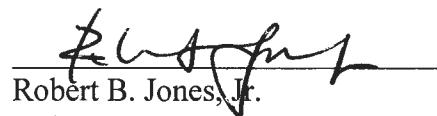
and credibility of ATSDR's scientific products." [DE-74-1] at ¶ 10.

On balance, though the draft CIS and supporting documents identified on Defendant's privilege log are undoubtedly relevant and solely in Defendant's possession, the public interest in both maintaining the integrity of ATSDR's peer review procedure and avoiding the damage resulting from premature release of any draft CIS outweighs Plaintiffs' need. Accordingly, the motion to compel is denied.

IV. Conclusion

For the foregoing reasons, Plaintiffs' motion to compel, [DE-64], is denied.

So ordered, the 19 day of December 2023.



Robert B. Jones, Jr.
United States Magistrate Judge